



7-2-04

IFW

Application No. (if known): 10/723,308

Attorney Docket No.: 04305/100M285-US1

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Information Disclosure Statement (4 pages);
Form PTO SB/08 (2 pages); and
Forty (40) documents.

Customer No.: 07278

Docket No.: 04305/100M285-US1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Henrik H. Jacobi et al.

Serial No.: 10/723,308

Filed: November 26, 2003

For: ALLERGEN DOSAGE FORM

July 1, 2004

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant Identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these

documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[x] 3. Cite Nos. BB, BC and BF are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- [x] The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[x] 5. Other information being provided for the examiner's consideration follows:

1. An International Search Report, dated March 3, 2004, which issued during the prosecution of International Application No. PCT/DK03/00784 which corresponds to the present application;

2. An International-Type Search Report dated October 24, 2004, which issued during the prosecution of Denmark Application No. DK 200300279 which corresponds to the present application; and

3. An International-Type Search Report dated July 14, 2003, which issued during the prosecution of Denmark Application No. DK 200201825 which corresponds to the present application, are enclosed.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication

indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.


CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

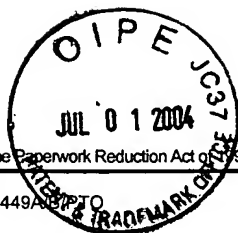
(1) U.S. Patent Application Serial No _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,


S. Peter Ludwig
Registration No. 25,351
Attorney for Applicant(s)

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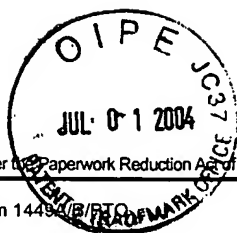
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/723,308
				Filing Date	November 26, 2003
				First Named Inventor	Henrik H. Jacobi
				Art Unit	3653
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	04305/100M285-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,371,516-B1	02-01-1983	Gregory et al.	
	AB	US-5,729,958-B1	03-24-1998	Kearney et al.	
	AC	US-5,343,672-B1	09-06-1994	Kearney et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	EP-0 346 622-A2	12-20-1989	Neo Abello SpA		
	BB	DE-107 208	07-20-1974	VEB Sachsches Serumwerk		
	BC	DE-101 37 232-A1	02-20-2003	Dr. Pierre Foss		
	BD	WO-00/44351-A1	08-03-2000	R.P. Sherer Corporation		
	BE	WO-00/61117-A1	10-19-2000	R.P. Scherer Corporation		
	BF	EP-0 278 877-A1	08-17-1988	Medibrevex Societe Civile Dite		
	BG	EP-0 271 079-A1	06-15-1988	Immunotec Inc.		
	BH	WO-97/39698-A1	10-30-1997	Manuel Guillen		
	BI	WO-01/39800-A2	06-07-2001	The Board of Trustees of the University of Arkansas and Panacea Pharmaceuticals LLC		
	BJ	WO-99/21579-A1	05-06-1999	R.P. Sherer Corporation		
	BK	WO-02/13858-A1	02-21-2002	Smithkline Beecham Biologicals S.A.		
	BL	WO-01/56611-A1	08-09-2001	Novartis Nutrition AG		
	BM	WO-00/51593-A2	09-08-2000	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		
	BN	WO-91/09591-A1	07-11-1991	Mediventures Inc.		
	BO	WO-00/51568-A1	09-08-2000	Laboratories Prographarm		
	BP	WO-99/47680-A1	09-23-1999	Alk-Abello A/S		
	BQ	WO-02/40676-A2	05-23-2002	Alk-Abello A/S		
	BR	WO-03/096869-A2	11-27-2003	Alk-Abello A/S		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/723,308	
			Filing Date	November 26, 2003	
			First Named Inventor	Henrik H. Jacobi	
			Art Unit	3653	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	2	Attorney Docket Number	04305/100M285-US1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Veb Sachsisches Serum, "Buccal medicament dosage forms - dissolving in the saliva and resorbed in the mouth", No. Abstract, DD-107208, XP-002257644	
	CB	J. Abecassis, et al., "Fabrication du medicament homeopathique", pages 77-99.	
	CC	Allergy Principles and Practice, Volume I, Fourth Edition, page 520.	
	CD	J. Ramirez et al., "Group 5 determination in Pooideae grass pollen extracts by monoclonal antibody-based ELISA. Correlation with biologic activity", Allergy, 1997: 52, 806-813.	
	CE	Henrik Ipsen, et al., "Allergenic Extracts", Basic Science, Part I, Chapter 20, pp. 540-547.	
	CF	Dr. Lars Haugaard, et al., "A controlled dose-response study of immunotherapy with standardized, partially purified extract of house dust mite: Clinical efficacy and side effects", J. Allergy Clin Immunol, Vol. 91, No. 3, pp. 709-722.	
	CG	ELISA COMPETITION ASSAY, Quantitative determination of relative potency of allergenic extracts, pp. 15-25.	
	CH	European Pharmacopoeia, Third Edition, No. 2.5.12, page 66.	
	CI	European Pharmacopoeia, Third Edition, page 356-358.	
	CJ	The European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, Committee for Proprietary Medicinal Products (CPMP), London, March 13, 1996, pp. 1-6.	
	CK	ICH Harmonised Tripartite Guideline, "Stability Testing of New Drug Substances and Products Q1A(R2)", International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, pp. 1-15.	
	CL	Dr. Stephen R. Durham et al., "Long-Term Clinical Efficacy of Grass-Pollen Immunotherapy", The New England Journal of Medicine, August 12, 1999, pp. 468-474.	
	CM	European Pharmacopoeia, Third Edition, 1997, Pharmaceutical Technical Procedures, pp. 134-135.	
	CN	MT Lima et al., "Grass pollen sublingual immunotherapy for seasonal rhinoconjunctivitis: a randomized controlled trial", Clin. Exp. Allergy, 2002, Apr. 32(4) Abstract	
	CO	CHR HANSEN GROUP, Improving the Quality of Food and Health for People all Over the World, Annual Report September 2001, pages 27-28	
	CP	Lowenstein, H. 1980 Arb Paul Ehrlich Institute 75:122-132.	
	CQ	An International Search Report, dated March 3, 2004, which issued during the prosecution of International Application No. PCT/DK03/00784	
	CR	An International-Type Search Report dated October 24, 2004, which issued during the prosecution of Denmark Application No. DK 200300279	
	CS	An International-Type Search Report dated July 14, 2003, which issued during the prosecution of Denmark Application No. DK 200201825	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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